

## Trinam® Successfully Completes First Stage of Phase II Study

## Preliminary data to be presented at ACS in October 2005 – Abstract awarded "Exceptional Merit"

**London, UK, 21 July 2005:** Ark Therapeutics Group plc ("Ark" and the "Company"), the emerging healthcare group, today announces that it has completed patient enrolment for the low dose arm of its Phase II study for Trinam<sup>®</sup> (EG004) and has received approval to move to the higher dose. Trinam<sup>®</sup> is Ark's novel therapy to prevent blood vessels blocking (intimal hyperplasia) after vascular graft access surgery in kidney failure patients.

The preliminary results of the first stage will be presented at the annual meeting of the American College of Surgeons (ACS) in San Francisco, October 16 - 20 2005. The abstract is one of twelve selected from the 309 abstracts initially submitted to have been awarded "Exceptional Merit", and one of only two in the vascular category.

The Phase II study in up to 20 patients, is taking place at three centres in the USA and is an open label ascending dose study, designed to examine the effects and safety of Trinam® in intimal hyperplasia prevention compared with standard care. Six patients were entered into the low dose stage and following review of the data, the company has been given clearance by the Data Safety Monitoring Board to proceed to the higher dose. The FDA has also given notification that six patients are adequate for the low dose stage. Earlier Phase I and pre-clinical studies with Trinam® have respectively demonstrated the first ever successful adventitial (from outside the blood vessel) gene transfer in humans and a significant effect in preventing intimal hyperplasia.

Trinam® is a combination of a Vascular Endothelial Growth Factor (VEGF) gene in an adenoviral vector and Ark's biodegradable collagen collar local delivery device (EG001). Trinam® is placed by the surgeon, at the end of surgery, around the join of the access graft and the vein, where blockages usually occur. The initial target market for Trinam® is haemodialysis graft access surgery, a treatment for kidney failure patients in which a plastic tube is grafted between blood vessels in the forearm to enable regular blood filtration. In the US and EU there are an estimated 150,000 cases a year where Trinam® might be used. Trinam® has been granted Orphan Drug Status by both the FDA and EMEA.

Dr Jeff Lawson, Principal Investigator, Duke University Medical Centre, commented: "We are through the first learning curve in using this novel product and the results to date look very interesting. If Trinam® is proven to help prolong the patency of haemodialysis access grafts, it would significantly improve the quality of life for these very sick and difficult to manage patients."

Dr Nigel Parker, CEO of Ark, commented: "We are pleased to have achieved this first trial milestone for Trinam® and we will now press on and enrol the second stage of the study. We look forward to presenting the data at the ACS meeting and are encouraged that the Phase I and main preclinical and bio-distribution studies were also accepted for presentation."

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